DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2004

Mr. Asher Kassel
Director of Regulatory Affairs
Mennen Medical, Ltd.
4 Hayarden Street, Yavne 81228
P.O. Box 102
Rehovot 76100
ISRAEL

Re: K030722
Trade/Device Name: Envoy Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Physiological Patient Monitor (with arrhythmia detection or alarms)
Regulatory Class: III
Product Code: MHX, BZK
Dated: January 14, 2004
Received: February 2, 2004

Dear Mr. Kassel:

This letter corrects our substantially equivalent letter of February 26, 2004, regarding the Envoy Patient Monitor. Our letter identified the regulation name as Continuous Ventilator. This is in error; the correct regulation name is Physiological Patient Monitor (with arrhythmia detection or alarms) as indicated above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting

your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number: K030722

Device Name: Envoy Patient Monitor

Indications for Use:

The Envoy is intended for use as a multiparameter monitoring system.

The Envoy can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure, etCO2 and Spirometry. This effectively allows the Envoy *to* monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

The Envoy also includes a spirometer intended for continuous monitoring of adult and pediatric patients with tidal volumes greater than 100mL. Functions include display of multiparameter waveforms, vital signs, and status messages.

Prescription Use **X** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K030722

FEB 2 6 2004

mennen medical

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Date: 24 February, 2004

Topic: **510(k) Safety and Effectiveness Summary as per 21 CFR Section 807.92(c)**
Envoy Patient Monitor - new Spirometry module:

Establishment Name, Registration Number and Address:

Name:	Mennen Medical Ltd.
Registration Number	9611022
Operator Number:	9011766
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Contact person: Asher Kassel, Director of Regulatory Affairs

To: Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk
From: Asher Kassel, Director of Regulatory Affairs

Product Name:
Proprietary: ENVOY
Common: Physiological Patient Monitor
Mennen Medical Part Number: 550-010-000 (full system)
554-000-010 (CPU only)

New Envoy Spirometry module P/N: 551-137-000

FDA Classification of Envoy Patient Monitor:

Classification Name:	Arrhythmia Detector and Alarm
Classification Number:	21 CFR 870.1025
Classification:	Class III
Product Code:	74 DSI

FDA Classification of new Spirometry module:

Classification Name:	Monitoring spirometer
Classification Number:	21 CFR 868.1850
Classification:	Class II
Product Code:	BZK

Performance Standards:
None promulgated

Voluntary Standards:
***IEC 60601-1**:
General Requirement for Safety for Medical Electrical Systems - part 1, (1988);
Amendment 1 – 1991-11;
Amendment 2 – 1995-03
***IEC 60601-1-2** (2001):
General Requirement for Safety
Collateral Standard: Electromagnetic compatibility - Requirements and tests.

Predicate Device:

METEOR Respiratory Mechanics Monitor(s) - K011784.

Device Description - Envoy Patient Monitor:

The Envoy is a multiparameter physiological patient monitor consisting of a main processing unit, a mountable color monitor, and a module rack housing the various Mennen Medical plug-in *vital signs* modules. The modules monitor the patient's vital signs. Up to six internal modules can be plugged into a module rack. The Envoy can accommodate two module racks. The vital sign data derived from the modules by the Envoy are presented on the monitor as waveform and numeric displays.

The Envoy vital signs modules acquire vital signs data from the patient, and display their waveforms and alarms indications on the Envoy display unit. Vital signs and waveform information are displayed simultaneously on the Envoy Display Unit. Up to 8 traces can be displayed at any one time.

The Envoy is a reusable, software driven, patient monitor, intended for use as part of a physiological monitoring system in a hospital environment. As such, it is not a life supporting, nor life-sustaining device; nor is it implantable and therefore sterility is not a consideration.

The Envoy is not a kit and does not contain any drug or biological products.
The **Spirometry** module of the Envoy patient monitor is not sold as a stand-alone spirometry device, but as part of a multiparameter physiological patient monitoring system (ENVOY).
In Chapter 1 of the Envoy Operating Manual, the following **Prescription Notice** appears: "Federal United States law restricts the sale and use of this instrument to qualified medical personnel only".

Intended Use and Functional Description and of the New Envoy Spirometry module:

Intended Use of the Spirometry module:

The Spirometry module is used to provide an objective measurement of lung function.
The Spirometry module is intended for use in the hospital clinical environment only (e.g. in the RICU). The module is used for the continuous monitoring of mechanically ventilated **adult** and **pediatric** patients; or for **adult** and **pediatric** patients able to breathe spontaneously. In both cases, breathing is via a tracheal tube or mask. The module is to be used only for patients with tidal volumes greater than 100 ml.

Functional Description:

The spirometry module can measure the following:

a) Expiratory Vital Capacity (EVC): The maximum volume of gas which can be expired from the lungs during a relaxed expiration from a position of full inspiration.

b) Inspiratory Vital Capacity (IVC): The maximum volume of gas which can be inspired into the lungs during a relaxed inspiration from a position of full expiration.
The expiratory phase is the one more commonly used to measure obstruction and restriction within the lungs.

Intended Use of the Envoy Patient Monitor:

The Envoy is intended for use as a multiparameter monitoring system.

The Envoy can monitor ECG/heart rate, two invasive blood pressure channels, two temperature channels, pulse oximetry, respiration, non-invasive blood pressure, etCO2 and Spirometry. This effectively allows the Envoy *to* monitor a wide-range of adult, pediatric and neonatal patient conditions, in many different areas of the hospital.

The Envoy also includes a spirometry module intended for continuous monitoring of adult and pediatric patients with tidal volumes greater than 100mL. Functions include display of multiparameter waveforms, vital signs, and status messages.

Summary of the technological characteristics of the new Envoy Spirometry module (incorporating OEM technology for a Respiratory Mechanics System):

The following tables summarize data on the Mennen Medical new Envoy Spirometry module:

Envoy Spirometry Module	
Part Number:	551-137-000
Monitored Parameters:	*Air Flow signal *Volume signal *Airway pressure
Module size:	**Single slot** Height: 10.0cm (4.0 in) Width: 4.0 cm (1.6 in) Depth: 14.0 cm (5.5 in)

Monitored parameters	Envoy Spirometry module
Vt_e	Yes
PIP	Yes
PEEP	Yes
MAP	Yes
Plat	Yes
PF_i	Yes
PF_e	Yes
RR	Yes
Ve	Yes
I:E	Yes
COMP	Yes
RES	Yes
RSBI	Yes

Alarm Indications	**Envoy Spirometry module**
Clinical Alarms for derived parameters	Visual & Sound Alarms

Specifications	**Envoy Spirometry module**
Degree of protection against electrical shock	Type BF applied part
Sampling	100 sps

OEM Airway Adapter/ Flow sensor	**Envoy Spirometry module**
Flow Range:	2 - 180 lpm (33 - 3000 ml/s)
Accuracy:	± 5 % reading, or 0.5 lpm
Dead Space:	6.9 ml
Connections:	Airway - 15 mm ID/22 mmOD patient end by 15 mm ID ventilator end (ISO 5356-1) Proprietary Smart connector. Tri-Tubing - triple 0.055" inch ID lumen
Length:	2.5 inches (adapter) - 6 feet (tubing)
Weight:	6.3 grams (minus tubing)
Material:	Sensor - Polycarbonate (Makrolon). Tubing - Medical grade Polyvinyl Chloride

Conclusion of comparison of technological characteristics:

We consider the Envoy Spirometry module to be substantially equivalent to the METEOR 200 Respiratory Mechanics Monitor; we submit that any differences between the two monitors do not raise any new issues of safety and effectiveness.

Testing

The Envoy Spirometry module has been subject to extensive safety and performance testing. Final testing for the system included various performance tests designed to ensure that the device meets all functional requirements and performance specifications. Safety testing and EMC testing were performed by an independent testing laboratory to ensure that the device complies to applicable industry and safety standards.

Signature: *Asher Kassel*

Asher Kassel
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